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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,856	06/23/2003	Joanna Hong Zhang	J6831(C)	8147

201 7590 03/08/2006

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 03/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/601,856	Applicant(s) ZHANG ET AL.	
	Examiner Sharmila S. Gollamudi	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of Amendments and Remarks and Information Disclosure Statement filed 11/16/05 is acknowledged. Claims **1-3 and 6** are pending in this application. Claims 4-5 stand cancelled.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 11/16/05 has been considered by the examiner with regard to US 20040146482; however EP 1262166 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jokura et al (5,641,495).

Jokura teaches a skin cosmetic containing having an excellent moisturizing effect comprising: (A) a ceramide or a pseudoceramide; (B) a dicarboxylic acid; and (C) a salt of a dicarboxylic acid. See abstract.

Jokura teaches examples of the dicarboxylic acid (B) include **malonic** acid, succinic acid, fumaric acid, maleic acid, glutaric acid, adipic acid, phthalic acid, and terephthalic acid . The dicarboxylic acid salt (C) include alkali metal (for example, sodium, potassium) salts; alkali earth metal (for example, calcium, magnesium) salts; alkanolamine (for example, **triethanolamine**) salts; basic amino acid (for example, lysine, arginine) salts and **ammonium** salts. These dicarboxylic acid salt may be added in the form of a salt at the step of the preparation of the skin cosmetic of the present invention. Alternatively, an acid may be added followed by the addition of an alkali (sodium hydroxide, etc.) to thereby form the aimed salt via *neutralization* in the system. To achieve a sufficient moisturizing effect while avoiding excessive irritation, it is preferable that the total content of these components (B) and (C), in terms of the acid, in the skin cosmetic of the present invention falls within a range of from 0.01 to 20% by weight, still preferably from 0.05 to 15% by weight and still preferably 0.01 to 10% by weight. To achieve a sufficient moisturizing effect while avoiding irritation due to the acid, it is preferable that the molar ratio of the components (B) to (C) falls within a range of from 1/9 to 9/1, still preferably from 2/8 to 8/2. See column 3, lines 30-60. Furthermore, Jokura teaches regulating the pH value of the skin cosmetic, which contains the components (B) and (C), to pH

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3 to 10, still preferably to pH 3 to 9, to avoid the irritation observed at a pH value less than 3 or exceeding 10. see column 3, lines 60-65.

When oily substances are used as the carrier, the content of the oily substance in is a range from 0.01 to 50% by weight. See column 4, lines 14-16. When water, ethanol and/or water-soluble polyhydric alcohols are employed as the carrier, the content is preferably from 0.01 to 95% by weight. See column 4, lines 30-35.

Specifically, example 3 teaches a sunscreen lotion comprising an organic acid, 0.5% of an organic acid salt (specifically sodium fumarate), and 2% 4,4-t-butyl-methoxybenzoylmethane (component ii with the instant UV range), among other components.

Jokura et al do not exemplify the instant malonic acid salt among the various dicarboxylic acid salts disclosed or the instant amine salts. Further, Jokura does not specify the acid to salt molar ratio.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Jokura et al and utilize the instant malonic acid salt in the sunscreen lotion of example 3 of Jokura. One would have been motivated to utilize the instant malonic acid salt versus the exemplified sodium fumarate (fumaric acid salt) of example 3 with a reasonable expectation of success since Jokura teaches **malonic** acid, succinic acid, **fumaric** acid, maleic acid, glutaric acid, adipic acid, phthalic acid, and terephthalic acid are *all* suitable dicarboxylic acid for the composition. Therefore, the selection of the instant acid salt is considered prima facie obvious since the prior art teaches that the criticality of selecting the acid is that it is a dicarboxylic acid and not the selection of the specific dicarboxylic acid itself.

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Regarding claims 2-3, although Jokura does not specify the molar ratio of acid: salt, it would have been obvious to a skilled artisan to manipulate this ratio. One would have been motivated to manipulate the ratio of the salt to acid since partial or full neutralization of the acid by the salt (salt acts as the neutralizing agent), adjusts the pH of the composition. Thus, one would have been motivated to utilize the desired acid: salt ratio depending on the desired pH of the composition. For instance, Jokura teaches the importance of avoiding skin irritation due to the acid; thus the pH must be above 3 and below 10 (see column 3, lines 30-65). Therefore, a skilled artisan would have been motivated to use a sufficient amount of salt to either partially or fully neutralize the acid in the composition to render a pH that does not irritant the skin wherein using equimolar amounts of the salt and acid (full neutralization) would increase the pH whereas partial neutralization of the acid would decrease the pH since the compound is in an acidic form. Additionally, it should be noted that generally differences in concentrations do not support the patentability of subject matter that is encompassed by the prior art unless there is evidence indicating such as concentration is critical. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Response to Arguments

Applicant's arguments filed 11/16/05 have been fully considered but they are not persuasive.

Applicant argues that Jokura does not “appreciate the special effectiveness of malonic acid salts” especially the selection of amine salts to control discoloration. Applicant argues that Jokura does not exemplify malonate salts and Jokura exemplifies fumaric acid. Applicant argues that Jokura does not teach the instant amines claimed. Further, applicant argues that applicant’s

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have demonstrated that the claimed amine salts have discoloration preventing properties over glycolic acid salts.

Firstly, the examiner points out that a reference need not exemplify an embodiment to anticipate an invention or render it obvious. Further, the fact that the examples do not utilize the embodiments is not a teaching away. "Disclosed examples and preferred embodiments do not constitute a teaching away from the broader disclosure or nonpreferred embodiment". In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971).

The examiner points out that malonic acid does not appear in a laundry list of acids to utilize and the acids taught by Jokura are sufficiently limited, i.e. about 8 species of suitable salts are taught. Further, Jokura teaches either utilizing alkali metals or amines "to form the aimed salt via neutralization in the system". Thus, again it is the examiner's position that although Jokura does not exemplify the amine salt, this does not constitute a teaching away from the amine salt form. Further, Jokura does teach an ammonium salt of the acid and applicant claims "*ammonia*, dimethylethanolamine, tris(hydroxymethyl)amino methane". The argument that ammonium is viewed as a generic term and includes diethylammonium and monethylammonium cations is unclear since Jokura only teaches "ammonium salts" which is implicit of the ammonium cation. Jokura does not disclose "ammonium salts such as diethylammonium and monethylammonium cations".

With regard to applicant's unexpected results disclosed in the instant specification, the examiner points out that the argued unexpected results do not address the instant prima facie obvious rejection. Applicant argues that the instant amine salts over other salt forms of the acid prevent discoloration; however applicant the examples applicant's relies on do not demonstrate

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this. Applicant needs to show the unexpectedness of the instantly claimed salts versus other salts. Further, applicant argues that Jokura's exemplified fumaric acid is different than the instantly claimed malonic acid and thus one would not be motivated to specifically select malonic acid; however applicant's examples compare glycolic acid and malonic acid. This is not a proper comparison since glycolic acid is not part of the Markush group of suitable salts taught by Jokura.

Therefore, it is the examiner's position that Jokura renders the instant invention *prima facie* obvious.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jokura et al (5,641,495) in view of JP 61215318 to Sadashige (entire document).

As set forth above, Jokura teaches a skin cosmetic containing having an excellent moisturizing effect comprising: (A) a ceramide or a pseudoceramide; (B) a dicarboxylic acid; and (C) a salt of a dicarboxylic acid. See abstract. Jokura teaches examples of the dicarboxylic acid (B) include **malonic** acid, succinic acid, fumaric acid, maleic acid, glutaric acid, adipic acid, phthalic acid, and terephthalic acid. The dicarboxylic acid salt (C) include alkali metal (for example, **sodium**, potassium) salts; alkali earth metal (for example, calcium, magnesium) salts; alkanolamine (for example, **triethanolamine**) salts; basic amino acid (for example, lysine, arginine) salts and **ammonium** salts. Specifically, example 3 teaches a sunscreen lotion comprising an organic acid, 0.5% of an organic acid salt, and 2% 4,4-t-butyl-methoxybenzoylmethane, among other components.

However, Jokura does not teach the instant sunscreen agent.

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Sadashige teaches a skin composition reducing discoloration and lowering UV-absorptivity. The composition contains (i) an organic acid or its salt wherein the acid may be selected from glyconic acid, ascorbic acid, succinic acid, citric acid, lactic acid, tartaric acid, butyric acid, oxalic acid, instant **malonic** acid, valeric acid, formic acid, acetic acid, or propionic acid; (ii) 4-(1,1-dimethylethyl)-4-methoxydibenzoylmethane (an organic sunscreen agent having a chromophoric group active within the ultraviolet radiation range of 280 to 400 nm and hereinafter referred to as Parsol 1789), and (iii) an emulsion base (carrier). It should be noted that 4-(1,1-dimethylethyl)-4-methoxydibenzoylmethane is also known as 4,4-t-butyl-methoxydibenzoylmethane as recited in dependent claim 6. The reference teaches the addition of the organic acid salt in combination with the instant sunscreen reduce discoloration of the composition. Generally the composition comprises 5% of Parsol 1789, 0-0.5% of the organic acid and/or salts, and a carrier in the instant amount. Preferably the organic acid and or salt is used in a range of 0.1-0.5%. See test example 1. The examples teach composition that comprise 1) the organic acid by itself, 2) the organic acid salt by itself, and 3) the combination of the organic acid and organic acid salt. Further, the examples utilize a sodium salt of the organic acid. For instance, examples 3 and 4 teach sodium citrate and example 1 teaches sodium lactate.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to look to combine the teaching of Jokura et al and Sadsahige and utilize the instant sunscreen agent. One would have been motivated to do so since Sadsahige teaches methoxydibenzoylmethane is an effective sunscreen agent. Thus, a skilled artisan would have been motivated to substitute Jokura's methoxydibenzoylmethane's derivative with the instantly

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claimed methoxydibenzoylmethane since Sadsahige teaches the instantly claimed sunscreen s an effective UV absorber.

Double Patenting

Claims 1-3 and 6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of copending Application No. 10/347982; 10/601731; 10/601819; 10/374300; 10/767679 is withdrawn in view of the filing of the Terminal Disclaimer on 10/11/05.

The rejection of claims 1, 4, and 6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 6 of U.S. Patent No. 5,961,961 in view of JP 61215318 to Sadashige is withdrawn in view of the amendments filed 11/16/05.

The rejection of claims 1, 4, and 6 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2, and 7 of U.S. Patent No. 6,495,123 in view of JP 61215318 to Sadashige (entire document) is withdrawn in view of the amendments filed 11/16/05.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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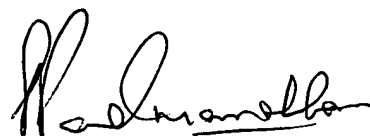
the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616



SHARMILA S. GOLLAMUDI
SUPERVISOR/INVENTOR